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Ukraine

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Procedures Adopted for Registration of GE Feeds and Vet Medicines

Report Categories:

Biotechnology and Other New Production Technologies

SP2 - Prevent or Resolve Barriers to Trade that Hinder

U.S. Food and Agricultural Exports

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Report Highlights:

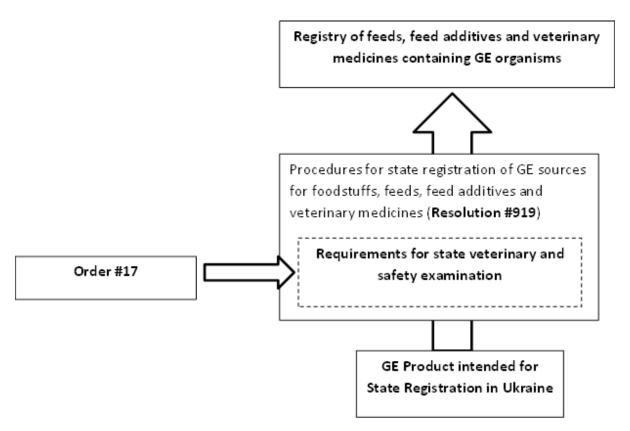
Through Order #17, published on January 16, 2018, Ukraine established procedures required for state veterinary and safety examination of genetically engineered (GE) organisms. The Order establishes, for the first time, transparent guidelines and procedures for soliciting official registration of feeds, feed additives, and veterinary medicines produced with GE content.

General Information:

The Ministry of Agricultural Policy and Food of Ukraine published Order #17 on January 16, 2018, (in <u>Ukrainian</u>), which establishes the procedures required for state veterinary and safety examination of feeds, feed additives and veterinary medicines containing GE organisms (Requirements).

These guidelines are the necessary key component (non-existent prior to Order #17) that indicate to interested parties how to solicit and attain official registration (approval) of GE events in foodstuffs, feeds, feed additives and veterinary medicines into the Registry of feeds, feed additives and veterinary medicines containing GE organisms (in Ukrainian). Please refer to page 9 of our Biotechnology Report for more details).

Please refer to the diagram below for a visualization of the registration process.



According to the guidelines, the applicant must submit a dossier to the State Food Safety and Consumer Protection Service of Ukraine (SFSCPS) containing the following:

- general information about the GE event and the product containing this GE event, including names, intended use, producer, safety certificates;
- specific information about the GE event including its specifications, permits from country of origin, methods of identification, safety testing and trial results, risk assessments, etc.;
- information about the applicant and the producer of the GE product, including packaging, commercial name, etc.

Upon receipt of a dossier, the SFSCPS forwards it to the <u>State Scientific and Research Control Institute</u> of <u>Veterinary Medicinal Products and Feed Additives</u> and the <u>State Scientific Control Institute of Biotechnology and Strains</u>. Within 90 days these institutions should provide a recommendation to the applicant whether the specific GE product can be registered in Ukraine. The applicant must then submit the recommendations from those institutions back to SFSCPS for registration of the GE product.

The remainder of the dossier for feeds, feed additives and veterinary medicines should contain:

- information about the applicant (name and contact data);
- common name of GE organism;
- commercial name of GE product;
- intended use of GE product;
- packaging type of GE product;
- methods of detection and identification;
- information about the producer of GE product (name and contact data).

SFSCPS has ten working days for registration of the GE product or to decline the application.

FAS-Kyiv Note: The information presented above provides a general explanation of registration procedures in place at the date of this report. FAS-Kyiv encourages all potential applicants to contact <u>SFSCPS</u> directly for clarification of all details before submitting an application. Applicants may also contact FAS-Kyiv for additional information.